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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,232	01/02/2004	Samuel Achilefu	MRD / 57CP	2153
26875	7590	12/29/2005	EXAMINER	
WOOD, HERRON & EVANS, LLP 2700 CAREW TOWER 441 VINE STREET CINCINNATI, OH 45202			JONES, DAMERON LEVEST	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/751,232

Applicant(s)

ACHILEFU ET AL.

Examiner

D. L. Jones

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

RESTRICTION INTO GROUPS

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1 and 5-10, drawn to 5-membered ring compositions of Formula 4 wherein both W4 and X4 are CRcRd, classified in class 548, subclass 100+.
 - II. Claims 1, 3, and 5-10, drawn to 5-membered ring compositions of Formula 4 wherein one of W4 or X4 is NRc and the other is CRcRd, classified in class 548, subclass 300.1+.
 - III. Claims 1, 2, and 5-10, drawn 5-membered ring compositions of Formula 4 wherein one of W4 or X4 is oxygen and the other is CRcRd, classified in class 549, subclass 200+.
 - IV. Claims 1 and 4-10, drawn to 5-membered ring compositions of Formula 4 wherein one of W4 or X4 is sulfur and the other is CRcRd, classified in class 549, subclass 1+.
 - V. Claims 3 and 5-10, drawn to 5-membered ring compositions of Formula 4 wherein both W4 and X4 are NRc, classified in class 548, subclass 300.1+.
 - VI. Claims 2, 3, and 5-10, drawn to 5-membered ring compositions of Formula 4 wherein one of W4 or X4 is NRc and the other is oxygen, classified in class 548, subclass 215+.

- VII. Claims 3-10, drawn to 5-membered ring compositions of Formula 4 wherein one of W4 or X4 is NRc and the other is sulfur, classified in class 548, subclass 146+.
- VIII. Claims 2 and 5-10, drawn to 5-membered ring compositions of Formula 4 wherein both W4 and X4 are oxygen, classified in class 548, subclass 215+.
- IX. Claims 2 and 4-10, drawn to 5-membered ring compositions of Formula 4 wherein one of W4 or X4 is oxygen and the other is sulfur, classified in class 548, subclass 146+.
- X. Claims 4-10, drawn to 5-membered ring compositions of Formula 4 wherein both W4 and X4 is sulfur, classified in class 548, subclass 146+.
- XI. Claims 1, 7, 8, 11, and 15-31, drawn to a diagnostic or therapeutic method comprising 5-membered ring compositions of Formula 4 wherein both W4 and X4 are CRcRd, classified in class 424+, subclass 9.1+.
- XII. Claims 1, 3, 7, 8, 11, 13, and 15-31, drawn to a diagnostic or therapeutic method comprising 5-membered ring compositions of Formula 4 wherein one of W4 or X4 is NRc and the other is CRcRd, classified in class 424+, subclass 9.1+.
- XIII. Claims 1, 7, 8, 11, 12, and 15-31, drawn to a diagnostic or therapeutic method comprising 5-membered ring compositions of Formula 4 wherein one of W4 or X4 is oxygen and the other is CRcRd, classified in class 424+, subclass 9.1+.

- XIV. Claims 1, 4, 7, 8, 11, and 14-31, drawn to a diagnostic or therapeutic method comprising 5-membered ring compositions of Formula 4 wherein one of W4 or X4 is sulfur and the other is CRcRd, classified in class 424+, subclass 9.1+.
- XV. Claims 3, 7, 8, 13, and 15-31, drawn to a diagnostic or therapeutic method comprising 5-membered ring compositions of Formula 4 wherein both W4 and X4 are NRc, classified in class 424+, subclass 9.1+.
- XVI. Claims 3, 7, 8, 12, 13, and 15-31, drawn to a diagnostic or therapeutic method comprising 5-membered ring compositions of Formula 4 wherein one of W4 or X4 is NRc and the other is oxygen, classified in class 424+, subclass 9.1+.
- XVII. Claims 3, 4, 7, 8, 13, and 14-31, drawn to a diagnostic or therapeutic method comprising 5-membered ring compositions of Formula 4 wherein one of W4 or X4 is NRc and the other is sulfur, classified in class 424+, subclass 9.1+.
- XVIII. Claims 2, 7, 8, 12, and 15-31, drawn to a diagnostic or therapeutic method comprising 5-membered ring compositions of Formula 4 wherein both W4 and X4 are oxygen, classified in class 424+, subclass 9.1+.
- XIX. Claims 2, 4, 7, 8, 12, and 14-31, drawn to a diagnostic or therapeutic method comprising 5-membered ring compositions of Formula 4 wherein one of W4 or X4 is oxygen and the other is sulfur, classified in class 424+, subclass 9.1+.

Art Unit: 1618

- XX. Claims 4, 7, 8, and 14-31, drawn to a diagnostic or therapeutic method comprising 5-membered ring compositions of Formula 4 wherein both W4 and X4 is sulfur, classified in class 424+, subclass 9.1+.

Note: Claims appearing in more than one group will only be examined to the extent that they read on the elected invention.

2. The inventions are distinct, each from the other because of the following reasons: Inventions (I & XI), (II & XII), (III & XIII), (IV & XIV), (V & XV), (VI & XVI), (VII & XVII), (VIII & XVIII), (IX & XIX), and (X & X) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the products may be used for diagnostic imaging as well as for therapeutic purposes. For example, the imaging techniques may be magnetic resonance imaging, ultrasound, x-ray, positron emission tomography, computed tomography, optoacoustic imaging, or single photon emission computed tomography. It should be noted that even though some of the inventions classify in the same area, a separate search of the art is necessary because each group is structurally different from one another. Thus, prior art which anticipates or renders one group obvious would neither anticipate nor render obvious another group.

Art Unit: 1618

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

REJOINDER PARAGRAPH

4. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re*

Art Unit: 1618

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

ELECTION OF SPECIES

5. Claims 1-31 are generic to a plurality of disclosed patentably distinct species comprising pharmaceutical compositions of Formula 4 wherein X4 and W4 are independently CRcRd, NRc, O, and S. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Note: Applicant is respectfully requested to elect a single disclosed species from within the elected group above. The elected species should include all variables associated with the elected species (i.e., R25-R36, b4, a4, Z4, Y4, etc.). In addition, Applicant is respectfully requested to state which claims read on the elected species.

6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Due to the complexity of the restriction requirement, a telephone call was not made to request an oral election to the above restriction requirement.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones
Primary Examiner
Art Unit 1618

December 23, 2005